**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**

UNITED STATES OF AMERICA, *ex rel.*
GLENN RZESZUTKO,
6548 Dunbarton Drive,
Hudson, OH 44236

BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA

c/o Hon. Bridget M. Brennan
Acting United States Attorney
801 West Superior Avenue, Suite 400
Cleveland, OH 44113

and

Hon. Monty Wilkinson
Acting United States Attorney General
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Plaintiff and Relator,

v.

RITE AID CORPORATION,
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801,

and

ELIXIR INSURANCE COMPANY f/k/a
ENVISION INSURANCE COMPANY
f/k/a ENVISION RX PLUS, INC.,
c/o A.G.C. Co.
127 Public Square, Suite 2000
Cleveland, OH 44114,

and

CASE NO. 5:21 CV 574

JUDGE JUDGE ADAMS

**COMPLAINT**

***Filed Under Seal Pursuant to 31 U.S.C. 3730(b)(2)***

MAG. JUDGE BURKE

***Do Not Serve***

***Do Not Put On PACER***

**JURY TRIAL DEMANDED**

ELIXIR RX OPTIONS, LLC, f/k/a RX OPTIONS, LLC, f/k/a RX OPTIONS, INC.,
c/o CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219,

and

ELIXIR RX SOLUTIONS, LLC, f/k/a ENVISION PHARMACEUTICAL SERVICES, LLC, f/k/a ENVISION PHARMACEUTICAL SERVICES, INC.,
c/o CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219,

and

JOHN DOES I – V, inclusive,

Defendants.

## INTRODUCTION

1. Relator Glenn Rzeszutko ("Relator") brings this action on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. § 3729, *et seq.*, to recover damages and civil penalties from Defendants Rite Aid Corporation ("Rite Aid"), Elixir Insurance Company f/k/a Envision Insurance Company f/k/a Envision RX Plus, Inc. ("EIC"), Elixir RX Options, LLC f/k/a RX Options, LLC f/k/a RX Options, Inc. ("ROI"), Elixir RX Solutions, LLC f/k/a Envision Pharmaceutical Services, LLC f/k/a Envision Pharmaceutical Services, Inc. ("EPS") (collectively, EIC, ROI, and EPS are referenced herein as "Envision"), and Does I-V (collectively, all defendants are referenced herein as "Defendants").

2. This action arises from Defendants' scheme to defraud the government by retaining millions of dollars of rebates provided by prescription drug manufacturers and deliberately

misclassifying them as "bona fide service fees" on their annual direct and indirect remuneration reports, causing the Medicare Part D program to overpay for prescription drugs and/or fail to recoup over $200 million.

3. Defendants made, or caused to be made, false or fraudulent claims to the federal Medicare program. Defendants also made false or fraudulent representations and certifications material to such claims in violation of the False Claims Act.

4. The United States has suffered millions of dollars in damages as a result of Medicare's payment of the false or fraudulent claims submitted and/or caused to be submitted by Defendants.

5. Prior to filing this Complaint, Relator provided the United States Attorney for the Northern District of Ohio a written Disclosure Statement of substantially all the material evidence and information in his possession related to the allegations in this Complaint in accord with 31 U.S.C. § 3730(b)(2). The Disclosure Statement includes the work product of Relator's attorneys and was submitted to the Attorney General and to the United States Attorney as potential co-counsel in the litigation pursuant to joint prosecution and common interest privileges. Therefore, this disclosure is confidential and privileged.

6. There has been no "public disclosure," as that term is defined in the False Claims Act, 31 U.S.C. § 3730(e)(4)(A), of the false claims or allegations herein.

7. Even if a public disclosure has occurred, Relator is an "original source" pursuant to 31 U.S.C. § 3730(e)(4)(B). Relator voluntarily disclosed to the Government the information on which the allegations or transactions involved in this litigation are based prior to any public disclosure. Additionally, Relator has knowledge that is independent of any such public disclosure and materially adds to the publicly disclosed allegations or transactions, and Relator voluntarily provided this information to the United Stated before filing this action.

## JURISDICTION AND VENUE

8. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729-3733. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345.

9. This Court has personal jurisdiction over all Defendants pursuant to 31 U.S.C. § 3732(a) because all Defendants can be found, reside, transact business, or committed acts proscribed by the False Claims Act within the State of Ohio and the United States.

10. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one of Defendants transacts business within this district and has committed acts proscribed by the False Claims Act within this district.

## PARTIES

11. Relator is a natural person residing in Ohio.

12. Defendant Rite Aid is a Delaware corporation that conducts business in Ohio.

13. Defendant EIC is an Ohio corporation that conducts business in Ohio.

14. Defendant ROI is an Ohio limited liability company that conducts business in Ohio.

15. Defendant EPS is an Ohio limited liability company that conducts business in Ohio.

16. The Doe Defendants are corporate entities of unknown structure and/or registration that are affiliated with the other Defendants and conduct business in Ohio.

## THE MEDICARE PART D PROGRAM

### A. Overview

17. Medicare Part D was established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, for the purpose of providing prescription drug coverage to individuals eligible for Medicare.

18. Unlike Parts A and B of the Medicare Act, Part D is a private, market-based program, in which the costs are shared between the government and private health insurers who offer prescription drug plans, provided those plans meet the requirements of the Medicare Part D Act and its regulations. Private health insurers that offer such plans are referred to as Part D Plan Sponsors ("Plan Sponsors"), and their Medicare Part D plans are referred to as Part D Plans.

19. The government agency responsible for administration of the Medicare Part D Program is the Centers for Medicare and Medicaid Services ("CMS"), which is under the aegis of the U.S. Department of Health and Human Services. 42 U.S.C. § 1395w-101, *et seq.*

20. Part D Plans are required to enter into contracts with CMS and must certify in their contract that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse.

21. Under Medicare Part D, plan beneficiaries pay premiums to participate in a Part D Plan. Beneficiaries obtain prescriptions from their health care provider and then obtain their medications from pharmacies. The dispensing pharmacy then seeks reimbursement from the beneficiary's Plan Sponsor. Plan Sponsors are reimbursed by Medicare for the cost of the covered drugs.

**B. Prescription Drug Costs and Rebates**

22. The list price paid for a drug by a Plan Sponsor to a pharmacy at the point of sale often does not reflect the actual, final cost of the drug to the Part D Plan because rebates and other price concessions are often offered by pharmaceutical manufacturers after the point of sale.

23. Pharmaceutical manufacturers offer rebates and other price concessions to Plan Sponsors and their intermediaries for a variety of reasons, including as an incentive to include manufacturer's drugs on the plan's formularies.

24. When a beneficiary obtains a prescription drug at a pharmacy, the Plan Sponsor pays the pharmacy the drug's list price (*e.g.*, $100), but the manufacturer may offer a rebate after the point of sale (*e.g.*, $20) which would reduce the Plan Sponsor's final cost of the drug (*e.g.*, $80).

25. Prescription drug rebates have increased considerably over the past decade, sometimes reaching 50 percent or more of the list price.

**C. Pharmacy Benefit Managers**

26. Part D Plan Sponsors subcontract with many entities to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with pharmacy benefit managers ("PBM").

27. PBMs are companies that manage prescription drug benefits on behalf of Part D Plans and other non-Medicare prescription drug plans. PBMs are used to aggregate the collective buying power of multiple plans to obtain lower prescription drug prices for the plans' beneficiaries. PBMs operate in the middle of the distribution chain by negotiating with prescription drug manufacturers for rebates and other discounts; developing and maintaining lists, or "formularies," of covered medications; contracting directly with individual pharmacies to reimburse the pharmacies for drugs dispensed to beneficiaries; and processing and paying prescription drug claims.

28. CMS regulations require that all subcontracts between Part D Plans and PBMs contain language obligating the PBM to comply with all applicable federal laws, regulations, and CMS instructions.

29. PBMs are compensated for the services they provide to Plan Sponsors in several ways, including administrative and service fees paid to them by the Plan Sponsors, and less commonly, by retaining a portion of the rebates provided by drug manufacturers in connection with the sale of prescription drugs.

**D. Bona Fide Service Fees**

30. In addition to the services they provide to Plan Sponsors on one side of the distribution chain, PBMs also sometimes provide fee-based services to drug manufacturers on the other side of the distribution chain. These services include rebate or program administration and data collection and often stem from the PBMs' ability to provide prescription drug manufacturers the convenience of having one point of contact for numerous Plan Sponsors which reduces the manufacturers' transaction costs. In exchange for these services, manufacturers sometimes pay PBSs what are called Bona Fide Service Fees ("BFSFs").

31. BFSFs are not tied to the purchase or sale of any drug but are paid by manufacturers to PBMs for performing certain itemized services.

32. In order for a fee to qualify as a BFSF, the fee must be paid by a manufacturer to a Part D Plan Sponsor or a PBM and must meet the definition of "bona fide service fees" provided at 42 CFR 423.501. Pursuant to that definition, a BFSF must meet all of the following conditions:

> 1) The fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer;
>
> 2) The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement;
>
> 3) The fee represents fair market value; and
>
> 4) The fee is not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug.

33. The purpose of these regulatory conditions is to ensure that BFSFs paid by manufacturers to PBMs are genuine fair-market-value fees for services provided and not rebates or other price concessions in disguise that affect the price of prescription drugs.

**E. Medicare Part D Reimbursement**

34. Reinsurance and risk-sharing are two of the payment mechanisms by which the Medicare Program reimburses Part D Plan Sponsors for providing prescription drug coverage. CMS is required by statute to base these payments on a Part D Plan Sponsor's "allowable reinsurance costs" and "allowable risk corridor costs," which must be "actually paid." As defined at 42 CFR 423.308, "actually paid" costs must be actually incurred by the Part D Plan Sponsor and net of any applicable direct or indirect remuneration ("DIR").

35. Section 1860D-15(f)(1)(A) of the Social Security Act requires Part D Plan Sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk-sharing. Therefore, Part D Plan Sponsors are required to report to CMS their drug costs and DIR associated with the Medicare prescription drug benefit. Consistent with section 1860D-15(d)(2)(A) of the Social Security Act, CMS's payments to a Part D Plan Sponsor are conditioned upon the Plan Sponsor's provision of this required data to CMS.

**F. Annual Part D Sponsor Bidding Process**

36. A Part D Plan Sponsor submits a bid to CMS in the year prior to the calendar year in which Part D benefits will actually be delivered to beneficiaries. The bid contains the Plan Sponsor's estimated per member per month ("PMPM") cost for providing Part D benefits to an average Medicare beneficiary in a particular geographic area.

37. From all of the bids that are submitted, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D Plan Sponsor's individual bid is higher than the benchmark, an enrolled beneficiary must pay the difference as part of a monthly premium. CMS then provides each Part D Plan Sponsor with *advance* monthly payments equal to

the Part D Plan Sponsor's standardized bid, risk adjusted for health status, minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies.

**G. Prescription Drug Event Reporting**

38. Each time a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Plan Sponsor for the costs not paid by the beneficiary (*i.e.,* the prescription drug costs in excess of the beneficiary's co-pay).

39. After receiving a claim, the Part D Plan Sponsor utilizes a record called a Prescription Drug Event ("PDE") to notify CMS that a prescription drug was purchased by and dispensed to a Part D beneficiary. The PDE includes the amount that the Plan Sponsor paid to the pharmacy. The PDE is an electronically created document that includes at least thirty-seven fields of information about a specific drug transaction.

40. At the end of the payment year, CMS uses the information in the PDEs to reconcile its *advance payments* to the Plan Sponsor with the *actual costs* the Plan Sponsor incurred for the prescription drugs. If a Part D Plan Sponsor's actual costs exceed the estimated costs, the Plan Sponsor may be able to recoup some of its losses through a risk sharing agreement with CMS. If a Part D Plan Sponsor's actual costs are lower than the previously estimated costs by a specified amount, payments to the Part D Plan Sponsor for the year are reduced and the Plan Sponsor will be required to pay back some of the estimated payments it received during the prior year.

41. As a condition for receiving its monthly payment from CMS, a Part D Plan Sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment. This data

may include enrollment information, claims data, bid submission data, and any other data specified by CMS.

42. If the claims data has been generated by a subcontractor of a Part D Plan Sponsor, such as a PBM, that subcontracting entity must "similarly certify" that the claims data it has generated is accurate, complete, and truthful, and must acknowledge that the data will be used to obtain federal reimbursement.

**H. Direct and Indirect Remuneration Reporting**

43. Because of rebates and other price concessions provided by manufacturers and pharmacies after the point of sale, the list price initially paid by a Part D Plan and recorded in a PDE often does not reflect the actual cost paid by the Part D Plan for the drug in question.

44. Therefore, in addition to the PDE reporting requirements described above, "[f]ees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs for Part D sponsors or PBMs must be reported to CMS as Direct or Indirect Remuneration [("DIR")]."[1]

45. Part D Plan Sponsors are required to submit annual DIR Submission Information, Summary DIR Reports, and Detailed DIR Reports (collectively, "DIR Reports") to CMS to document price concessions (*e.g.*, drug manufacturer rebates) that ultimately impact the gross prescription drug costs of Medicare Part D plans but that are not captured at the point of sale.

46. DIR Reports are used by CMS in tandem with PDE data to "true up" what is paid to a Part D Plan Sponsor by CMS for a given plan year.

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[1] *Fact Sheet, Medicare Part D—Direct and Indirect Remuneration (DIR)*, CMS.gov (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

47. CMS relies on this dual-reporting system in order to make sure its payments to Plan Sponsors are accurate:

> The Part D reconciliation process, in particular, is dependent on transaction data summarized on [PDE] records. . . . [but] [o]ften, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. Examples of such compensation include rebates provided by manufacturers and concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans. . . .
>
> Part D sponsors and PBMs are engaging to a greater extent in arrangements that feature compensation after the point-of-sale, and the value of such compensation is also generally increasing. As a result, CMS has observed a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all DIR.
>
> DIR results from payment arrangements negotiated independent of CMS, between Part D sponsors, PBMs, network pharmacies, drug manufacturers, and other parties involved in the administration of the Part D benefit. . . .
>
> *The final plan payments by CMS are, per statute, to be based on the costs actually incurred by Part D sponsors. These actual costs must reflect any applicable DIR*. DIR is apportioned only between Medicare and the Part D plan, generally based on the share of the total Part D drug costs that each is responsible for over the course of the payment year.[2]

48. Failure to accurately report and account for DIR as required results in Medicare paying more than is actually owed to a Part D Plan Sponsor and/or recouping less than would be appropriate.

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[2] *Id.* (emphasis added).

49. Per the regulations at 42 CFR 423.308, DIR is any form of price concession, received from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) by either by the Part D Plan Sponsor or by an intermediary contracting organization, such as a PBM with which the sponsor has contracted, that serves to decrease the costs incurred under the Part D plan by the Part D Plan Sponsor, either directly or indirectly.

50. DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale.[3]

51. Price concessions meeting the above criteria are required by CMS to be reported as DIR in the Summary and Detailed DIR Reports regardless of whether the intermediary contracting organization (*e.g.*, the PBM) retains all or a portion of the price concession or passes through the entire amount to the Plan Sponsor.[4]

52. CMS specifies that PBM-retained rebates constitute DIR and must be reported as such.[5]

53. While any remuneration that directly or indirectly affects drug costs, such as rebates, must be reported as DIR, other price concessions or payments that do not directly or indirectly impact drug costs incurred by the Part D Plan Sponsor are not considered DIR and do not need to be reported as such.[6]

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[3] *See* CMS, *Revised Final Medicare Part D DIR Reporting Requirements for 2018*, p. 6 (April 30, 2019).

[4] *Id.*

[5] *Id.*

[6] *Id.*

54. Among the payments that CMS specifically recognizes as *not* constituting DIR are BFSFs that Plan Sponsors or PBMs receive from pharmaceutical manufacturers.[7]

55. While BFSFs are not considered DIR, they must nevertheless be reported to CMS on Plan Sponsors' DIR Reports in a separately designated non-DIR section.[8]

56. In order for a fee to be properly reported as a BFSF and thus not be considered DIR, the fee must be paid by a manufacturer to a Part D Plan or a PBM and must meet the definition of "bona fide service fees" provided at 42 CFR 423.501, set forth above.[9]

57. CMS requires that the Part D Plan Sponsor "must maintain documentation supporting the evaluation of the above criteria for bona fide service fees."[10]

58. According to CMS, "[t]he element of 'fair market value' means the manufacturer must pay the Part D sponsor or PBM the same rate for performing these services that it would have paid had the services been performed by other or similarly situated entities."[11]

59. CMS requires that "[m]anufacturers must determine the fair market value themselves, using the most appropriate, industry-accepted method, which we believe manufacturers are well-equipped to identify."[12]

60. CMS further requires that "[d]ocumentation of the fair market value analysis needs to be maintained by the [Part D Plan Sponsor,]" and that "[t]his documentation shall include, at a minimum, assumptions, methodology, and rationale used to determine fair market value."[13]

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[7] *Id.* at pp. 6, 27-28.

[8] *Id.*

[9] *Id.* at p. 27.

[10] *Id.* at p. 28.

[11] *Id.* at p. 27.

[12] *Id.*

[13] *Id.*

## ENVISION ORGANIZATIONAL STRUCTURE

61. The Defendants are affiliated entities involved in the pharmaceutical services and insurance industry.

62. EIC, ROI, EPS, and Does I – V are and have since 2015 been wholly-owned subsidiaries of Rite Aid.

63. ROI and EPS function as PBMs.

64. ROI and EPS divide up the different aspects of services typically offered by a PBM and contract with each other to provide those services for their clients. ROI manages all the provider contracts with pharmacies (addressing, *inter alia*, drug pricing and distribution) and employs all the employees for the Envision companies. EPS, on the other hand, has all the trade contracts with pharmaceutical manufacturers (addressing, *inter alia*, rebates and formularies).

65. All non-affiliated Part D and commercial insurance plan clients contract directly with EPS as their PBM, which in turn subcontracts with ROI to provide its pharmacy network.

66. In 2007, Envision formed its own insurance company, Envision Insurance Company ("EIC"), as a wholly-owned subsidiary.

67. Upon inception, EIC applied to CMS and was granted a Medicare Part D Plan.

68. Unlike all of Envision's non-affiliated insurance plan clients, EIC contracts directly with ROI as its PBM. ROI then subcontracts with EPS to negotiate and manage EIC's contracts and dealings with pharmaceutical manufacturers.

69. EIC is the only insurance plan that contracts directly with ROI.

70. Defendant Rite Aid purchased Envision in 2015. Ride Aid oversees and controls all operations of Envision and is the ultimate parent of all the Defendants herein.

71. Relator was the Vice President of Finance and subsequently the Chief Underwriting Officer for Envision from June 2008 through September 30, 2019 and has personal knowledge of the fraudulent scheme described herein.

## ENVISION'S FRAUDULENT SCHEME

72. At least since 2015, Defendants have been intentionally defrauding the Medicare Part D program by falsely reporting as BFSFs on EIC's annual DIR reports amounts that are not BFSFs but are actually manufacturer rebates being retained by EPS.

73. Specifically, Defendants developed a scheme whereby EPS has been retaining 20% of all manufacturer rebates for prescription drugs provided to EIC's Part D plan beneficiaries (hereinafter, the "Retained Rebates"), and EIC has been knowingly and falsely reporting the Retained Rebates as BFSFs each year on its DIR reports, instead of reporting them as DIR as it is required to do.

74. This scheme enables EIC's affiliate EPS to keep the entirety of its retained rebate amounts as profit instead of passing the rebate savings on to Medicare as required.

75. Though EPS serves as the PBM for multiple insurance plans, it only retains these rebates in connection with its affiliate Part D Plan Sponsor, EIC.

76. Defendants' reporting of the Retained Rebates as BFSFs is in violation of CMS's DIR reporting requirements, which expressly require PBM-retained rebates to be reported as DIR and also require compliance with specific criteria to qualify as a BFSF.

77. The Retained Rebates do not satisfy the legal requirements to be considered BFSFs.

78. Because EIC is falsely reporting the Retained Rebates as BFSFs and not as DIR, Defendants are depriving Medicare of amounts that Medicare is entitled to recover.

79. EIC has fraudulently reported Retained Rebates as BFSFs in the range of $58 million to $65 million each year since 2016.

80. Defendant Rite Aid was aware of the scheme to fraudulently report Retained Rebates as BSFSs. The scheme was reported to John Standley (Rite Aid CEO) and Darren Karst (Rite Aid CFO) and other Rite Aid executives. Standley and Karst expressed some concern about the scheme but did not prohibit it. Because of Standley and Karst's concern about the fraudulent scheme, it was only utilized with the affiliated EIC and not any unaffiliated Plan Sponsor clients.

81. The Retained Rebates are price concessions that change (*i.e.,* reduce) the cost for prescription drugs provided to EIC's Part D beneficiaries.

82. The amounts of the Retained Rebates are not related to or determined based upon the quantity and value of any itemized services provided by EIC, but rather are tied directly to rebates given by manufacturers on drugs provided to EIC's Part D beneficiaries—*i.e.*, EPS has retained a flat 20% of all rebates.

83. The Retained Rebates are not in exchange for any bona fide, itemized services actually performed by EPS on behalf of any pharmaceutical manufacturer.

84. Even if they were in exchange for some bona fide, itemized services actually performed by EPS on behalf of pharmaceutical manufacturers, the Retained Rebates far exceed fair market value for any such services.

85. Upon information and belief, the pharmaceutical manufacturers with which EPS has contracted are not aware that EPS is retaining 20% of rebates as purported BFSFs for services purportedly provided on their behalf.

86. Upon information and belief, none of EPS's contracts with pharmaceutical manufacturers reference or provide for the Retained Rebates as purported BFSFs.

87. Upon information and belief, none of the pharmaceutical manufacturers with which EPS has contracted have conducted any fair market value analyses in connection with the Retained Rebates that Defendants are claiming as BFSFs.

88. Upon information and belief, none of the pharmaceutical manufacturers with which EPS has contracted have provided any documentation of any fair market value analysis in connection with the Retained Rebates that Defendants are claiming as BFSFs.

89. Instead of maintaining documentation of fair market value analysis prepared by manufacturers as required by CMS, Defendants have instead been fabricating their own documents in an effort to justify the Retained Rebates that Defendants are claiming as BFSFs (hereinafter, the "Fabricated FMV Documentation").

90. Defendants have created and are maintaining the Fabricated FMV Documentation in an attempt to support their fraudulent misclassification of the Retained Rebates as BFSFs in the event of an audit.

91. Because of Relator's former position with the Defendants, Relator witnessed and has personal knowledge of the DIR reports submitted by EIC to CMS each year from 2016 through 2019.

92. Upon information and belief, Defendants did not change their practice for the 2019 DIR report, which would have been submitted in or about July 2020.

**SPECIFIC FLASE CLAIMS**

93. On or before June 30, 2016, EIC submitted DIR Reports to CMS for 2015 (the "2015 DIR Reports").

94. Bill Epling ("Epling"), President of EIC, signed the 2015 DIR Reports on behalf of EIC and certified that the information reported therein was true and accurate.

95. In the 2015 DIR Reports, EIC reported approximately $58 million as BFSFs.

96. The approximately $58 million that EIC reported as BFSFs in its 2015 DIR Reports were not actually BFSFs but were manufacturer rebates retained by EPS.

97. The approximately $58 million that EIC reported as BFSFs in its 2015 DIR Reports did not satisfy the criteria for BFSFs provided at 42 CFR 423.501.

98. EIC knew that its reporting of the approximately $58 million of Retained Rebates as BFSFs on its 2015 DIR Reports was false.

99. EIC failed to report the approximately $58 million of Retained Rebates as DIR anywhere else on the 2015 DIR Reports.

100. Defendants did not obtain any fair market value analysis or documentation from any manufacturer in connection with the approximately $58 million EIC claimed as BFSFs on its 2015 DIR Reports.

101. As a result of Defendants' false and fraudulent reporting in connection with the 2015 DIR Reports, Defendants have been overpaid by and have failed to repay Medicare in the amount of approximately $58 million.

102. On or before June 30, 2017, EIC submitted DIR Reports to CMS for 2016 (the "2016 DIR Reports").

103. Epling signed the 2016 DIR Reports on behalf of EIC and certified that the information reported therein was true and accurate.

104. In the 2016 DIR Reports, EIC reported approximately $60 million as BFSFs.

105. The approximately $60 million that EIC reported as BFSFs in its 2016 DIR Reports were not actually BFSFs, but were manufacturer rebates retained by EPS.

106. The approximately $60 million that EIC reported as BFSFs in its 2016 DIR Reports did not satisfy the criteria for BFSFs provided at 42 CFR 423.501.

107. EIC knew that its reporting of the approximately $60 million of Retained Rebates as BFSFs on its 2016 DIR Reports was false.

108. EIC failed to report the approximately $60 million of Retained Rebates as DIR anywhere else on the 2016 DIR Reports.

109. Defendants did not obtain any fair market value analysis or documentation from any manufacturer in connection with the approximately $60 million EIC claimed as BFSFs on its 2016 DIR Reports.

110. As a result of Defendants' false and fraudulent reporting in connection with the 2016 DIR Reports, Defendants have been overpaid by and have failed to repay Medicare in the amount of approximately $60 million.

111. On or before June 30, 2018, EIC submitted DIR Reports to CMS for 2017 (the "2017 DIR Reports").

112. Epling signed the 2017 DIR Reports on behalf of EIC and certified that the information reported therein was true and accurate.

113. In the 2017 DIR Reports, EIC reported approximately $62 million as BFSFs.

114. The approximately $62 million that EIC reported as BFSFs in its 2017 DIR Reports were not actually BFSFs, but were manufacturer rebates retained by EPS.

115. The approximately $62 million that EIC reported as BFSFs in its 2017 DIR Reports did not satisfy the criteria for BFSFs provided at 42 CFR 423.501.

116. EIC knew that its reporting of the approximately $62 million of Retained Rebates as BFSFs on its 2017 DIR Reports was false.

117. EIC failed to report the approximately $62 million of Retained Rebates as DIR anywhere else on the 2017 DIR Reports.

118. Defendants did not obtain any fair market value analysis or documentation from any manufacturer in connection with the approximately $62 million EIC claimed as BFSFs on its 2017 DIR Reports.

119. As a result of Defendants' false and fraudulent reporting in connection with the 2017 DIR Reports, Defendants have been overpaid by and have failed to repay Medicare in the amount of approximately $62 million.

120. On or before June 30, 2019, EIC submitted DIR Reports to CMS for 2018 (the "2018 DIR Reports").

121. Epling signed the 2018 DIR Reports on behalf of EIC and certified that the information reported therein was true and accurate.

122. In the 2018 DIR Reports, EIC reported approximately $65 million as BFSFs.

123. The approximately $65 million that EIC reported as BFSFs in its 2018 DIR Reports were not actually BFSFs, but were manufacturer rebates retained by EPS.

124. The approximately $65 million that EIC reported as BFSFs in its 2018 DIR Reports did not satisfy the criteria for BFSFs provided at 42 CFR 423.501.

125. EIC knew that its reporting of the approximately $65 million of Retained Rebates as BFSFs on its 2018 DIR Reports was false.

126. EIC failed to report the approximately $65 million of Retained Rebates as DIR anywhere else on the 2018 DIR Reports.

127. Defendants did not obtain any fair market value analysis or documentation from any manufacturer in connection with the approximately $65 million EIC claimed as BFSFs on its 2018 DIR Reports.

128. As a result of Defendants' false and fraudulent reporting in connection with the 2018 DIR Reports, Defendants have been overpaid by and have failed to repay Medicare in the amount of approximately $65 million.

**COUNT ONE**
**False Claims Act: Presentation of False Claims in Violation of 31 U.S.C. § 3729(a)(1)(A)**

129. Relator realleges and incorporates the preceding paragraphs as if set forth fully herein.

130. Defendants, personally and by and through their officers, members, agents, and employees, authorized their various officers, members, agents, and employees to take the actions relating to the conduct alleged above.

131. As a result of the schemes described above, including but not limited to the false reporting of the Retained Rebates as BFSFs on their DIR Reports, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment to the United States and/or the United States' contractors, grantees, or other recipients in violation of 31 U.S.C. § 3729(a)(1)(A).

132. Defendants "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendants acted with actual knowledge of the alleged information, in deliberate disregard of the truth or falsity of the alleged information, and/or in reckless disregard of the truth or falsity of the alleged information.

133. As a result, the United States suffered actual damages in an amount to be determined at trial.

**COUNT TWO**
**False Claims Act: False Records or Statements in Violation of 31 U.S.C. § 3729(a)(1)(B)**

134. Relator realleges and incorporates the preceding paragraphs as if set forth fully herein.

135. Defendants, personally and by and through their officers, members, agents, and employees, authorized their various officers, members, agents, and employees to take the actions relating to the conduct alleged above.

136. Due to their schemes described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent statements material to false or fraudulent claims to the United States and/or the United States' contractors, grantees, or other recipients, in violation of 31 U.S.C. § 3729(a)(1)(B).

137. Defendants "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendants acted with actual knowledge of the alleged information, in deliberate disregard of the truth or falsity of the alleged information, and/or in reckless disregard of the truth or falsity of the alleged information.

138. As a result, the United States suffered actual damages in an amount to be determined at trial.

**COUNT THREE**
**False Claims Act: Conspiracy in Violation of 31 U.S.C. § 3729(a)(1)(C)**

139. Relator realleges and incorporates the preceding paragraphs as if set forth fully herein.

140. Defendants, personally and by and through their officers, members, agents, and employees, authorized their various officers, members, agents, and employees to take the actions relating to the conduct alleged above.

141. By their actions as detailed above, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G).

142. Defendants had a singular conspiratorial plan, which was for EPS to retain 20% of manufacturer rebates only for drugs provided to its affiliate EIC's Medicare Part D beneficiaries and for EIC to falsely claim those Retained Rebates as BFSFs on its annual DIR Reports, so as to enable Defendants to keep those Retained Rebates and deprive Medicare of its right to recover those Retained Rebates.

143. To achieve their shared conspiratorial plan, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented false or fraudulent claims for payment to the United States and/or the United States' contractors, grantees, or other recipients in violation of 31 U.S.C. § 3729(a)(1)(A).

144. As detailed above, Defendants each performed overt acts in furtherance of their conspiracy to violate 31 U.S.C. § 3729(a)(1)(A).

145. Also to achieve their shared conspiratorial plan, Defendants conspired to commit violations of 31 U.S.C.§ 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims to the United States and/or the United States' contractors, grantees, or other recipients, in violation of 31 U.S.C. §3729(a)(1)(B).

146. As detailed above, Defendants each performed overt acts in furtherance of their conspiracy to violate 31 U.S.C. § 3729(a)(1)(B).

147. Also to achieve their shared conspiratorial plan, Defendants conspired to commit violations of 31 U.S.C.§ 3729(a)(1)(G) by knowingly making, using, or causing to be made or used, false records or statements material to an obligation to pay or transmit money or property to

the Government, and knowingly concealing and/or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

148. As detailed above, Defendants each performed overt acts in furtherance of their conspiracy to violate 31 U.S.C. § 3729(a)(1)(G).

149. Defendants "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendants acted with actual knowledge of the alleged information, in deliberate disregard of the truth or falsity of the alleged information, and/or in reckless disregard of the truth or falsity of the allege information.

150. As a result of the Defendants' conspiracy, the United States suffered actual damages in an amount to be determined at trial.

**COUNT FOUR**
**Reverse False Claims in Violation of 31 U.S.C. § 3729(a)(1)(G)**

151. Relator realleges and incorporates by reference the allegations previously alleged herein.

152. Defendants, personally and by and through their officers, members, agents, and employees, authorized their various officers, members, agents, and employees to take the actions relating to the conduct alleged above.

153. Due to their schemes described above, including but not limited to the false reporting of the Retained Rebates as BFSFs on their DIR Reports, Defendants knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government and knowingly concealed and/or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729(a)(1)(G).

154. The United States, unaware of the false or fraudulent nature of these claims, paid such claims when it would not otherwise have paid had it known the truth.

155. Defendants "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendants acted with actual knowledge of the alleged information, in deliberate disregard of the truth or falsity of the alleged information, and/or in reckless disregard of the truth or falsity of the alleged information.

156. As a result, the United States suffered actual damages in an amount to be determined at trial.

## PRAYER FOR RELIEF

**WHEREFORE,** Relator, on behalf of Relator and the United States of America, prays as follows:

(a) That this Court enter judgment against Defendants jointly and severally in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $5,500.00 to $11,000.00 (or in such other amount as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 pursuant to 31 U.S.C. § 3729(a)(1)) for each action in violation of 31 U.S.C. § 3729(a), and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

(b) That Relator be awarded all costs incurred, including reasonable attorneys' fees and expenses, in accord with 31 U.S.C. § 3730(d);

(c) That, in the event the United States Government elects to intervene in and proceed with this action, Relator be awarded between 15% and 25% of the proceeds of the action or of any settlement in accord with 31 U.S.C. § 3730(d)(1);

(d) That, in the event that the United States Government does not intervene in and proceed with this action, Relator be awarded between 25% and 30% of the proceeds of the action or of any settlement in accord with 31 U.S.C. § 3730(d)(2);

(e) That, pursuant to 31 U.S.C. § 3730(c)(5), Relator be awarded a share of any alternate remedy that the United States Government elects to pursue;

(f) That permanent injunctive relief be granted to prevent any recurrence of the conduct described above for which redress is sought in this Complaint;

(g) That the United States and Relator be awarded prejudgment and post judgment interest; and

(h) That the United States and Relator receive all relief, both at law and in equity, to which they may be reasonably entitled.

Respectfully submitted,

**ROLF GOFFMAN MARTIN LANG LLP**

*/s/ Joseph F. Petros III*

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*Counsel for Relator*

**JURY DEMAND**

A trial by jury is hereby demanded.

*/s/ Joseph F. Petros III*

Joseph F. Petros III (OH 0088363)